Markup Form

1. (amended) A puncture and cut resistant material comprising:

a plurality of substantially spherical macrospheres, each macrosphere comprising:

a plurality of substantially spherical microspheres [aggregated together]; and

a polymer [coating] surrounding and aggregating the microspheres together to form the substantially spherical macrosphere

[;

wherein the polymer coating over the aggregated microspheres forms a macrosphere having a substantially smooth spherical surface].

3. (amended) The puncture and cut resistant material of claim 1 [wherein] further comprising for each of the plurality of macrospheres:

a plurality of capture devices, each capture device comprising [each] an area between adjacent microspheres and the polymer [coating] surrounding [in] the [area between] adjacent microspheres [forms a capture device]; and

wherein the plurality of microspheres and surrounding polymer [coating] create a [contiguous set] plurality of capture devices surrounding the macrosphere; and

wherein each capture device is adapted to capture a point of an invading sharp instrument.

11. (amended) A puncture and cut resistant material comprising:

a plurality of substantially spherical macrospheres, each macrosphere comprising:

a substantially spherical porous structure

having a porous surface comprising a plurality of [with] random pores; and

a polymer coating over the porous structure;

wherein the polymer coating over the porous structure forms a substantially spherical macrosphere having a substantially smooth surface.

12. (amended) The puncture and cut resistant material of claim 11 [wherein] further comprising for each of the plurality of macrospheres:

a plurality of capture devices, each capture device comprising:

[each] one of the plurality of random [pore] pores and the polymer coating over the random pore [macrospheres forms a capture device];

wherein [the] each capture device is adapted to capture a point of an invading sharp instrument.

18. (amended) A puncture and cut resistant surgical glove comprising:

a plurality of overlaying arrays of adjacent substantially spherical macrospheres, each macrosphere having a plurality of capture devices, each capture device adapted to capture a point of an invading sharp instrument;

wherein each substantially spherical macrosphere having a plurality of capture devices comprises:

a plurality of microspheres; and

a polymer surrounding and aggregating the microspheres together;

wherein each capture device comprises an area between adjacent microspheres and the polymer surrounding the adjacent microspheres;

wherein the plurality of microspheres and surrounding polymer create a plurality of capture devices

surrounding the macrosphere; and

wherein each capture device is adapted to capture a point of an invading sharp instrument; and

an elastomer encapsulating the plurality of overlaying arrays of adjacent macrospheres.

23. (amended) A method of producing a puncture and cut resistant material comprising the steps of:

forming a plurality of substantially spherical macrospheres, each macrosphere having a plurality of capture devices, each capture device adapted to capture a point of an invading sharp instrument; and

injecting the macrospheres and an elastomer into an injection mold.

24. (amended) The method of claim 23 for producing a puncture and cut resistant material wherein the steps of forming a plurality of substantially spherical macrospheres [, each macrosphere having capture devices] comprises the steps of:

spraying droplets of molten alumina;

cooling the droplets to form microspheres;

spraying [a] droplets of a solution of microspheres and liquefied polyethylene; and

cooling the droplets to form macrospheres, each macrosphere comprising aggregated microspheres coated with polyethylene.

25. (amended) The method of claim 23 for producing a puncture and cut resistant material wherein the steps of forming a plurality of substantially spherical macrospheres [, each macrosphere having capture devices] comprises the steps of:

spraying droplets of molten alumina and a second material that volatizes at a lower temperature than the alumina;

cooling the droplets to form porous macrospheres;

tumbling the porous macrospheres with an abrasive to open up the surface and remove any intact surface film of alumina;

spraying [a] droplets of a solution of porous macrospheres and liquefied polyethylene; and

cooling the droplets to form polyethylene coated porous macrospheres;

wherein when the second material volatizes at the lower temperature, bubbles are formed in the droplets forming the porous macrospheres.

26. (amended) A method of producing a puncture and cut resistant material comprising the steps of:

forming magnetically sensitive substantially spherical macrospheres, each macrosphere having a plurality of capture devices, each capture device adapted to capture a point of an invading sharp instrument;

dipping a former comprising electro-magnetic elements into a solution of the magnetically sensitive macrospheres and an elastomer; and

activating the electro-magnetic elements;

whereby activating the electro-magnetic elements draws the magnetically sensitive macrospheres onto surfaces of the former.

27. (amended) The method of claim 26 for producing a puncture and cut resistant material wherein the steps of forming substantially spherical magnetically sensitive macrospheres [, each macrosphere having capture devices] comprises the steps of:

spraying droplets of molten alumina comprising a magnetically sensitive material;

cooling the droplets to form microspheres;

spraying [a] droplets of a solution of microspheres and

liquefied polyethylene; and

cooling the droplets to form macrospheres, each macrosphere comprising aggregated microspheres coated with polyethylene.

28. (amended) The method of claim 26 for producing a puncture and cut resistant material wherein the steps of forming substantially spherical macrospheres [, each macrosphere having capture devices] comprises the steps of:

spraying droplets of molten alumina comprising a magnetically sensitive material and a second material that volatizes at a lower temperature than the alumina;

cooling the droplets to form porous magnetically sensitive macrospheres;

tumbling the porous magnetically sensitive macrospheres with an abrasive to open up the surface and remove any intact surface film of alumina;

spraying [a] droplets of a solution of porous magnetically sensitive macrospheres and liquefied polyethylene; and

cooling the droplets to form polyethylene coated porous magnetically sensitive macrospheres;

wherein when the second material volatizes at the lower temperature, bubbles are formed in the droplets forming the porous magnetically sensitive macrospheres.

REMARKS

The Examiner has rejected Claims 1-3, 5, 11, 12, 14, 19, 20, 22, and 23 under 35 U.S.C. 102(b) as being anticipated by Darras (USPN 5,817,433). The Examiner has also rejected Claims 1-6, 11-15, and 23 under 35 U.S.C. 102(b) as being clearly anticipated by Oakley et al (USPN 6,080,474). Claims 7-10, 16-22, and 24-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Oakley et al (USPN 6,080,474).

With regard to Claims 1-3, 5, 11, 12, 14, 19, 20, 22, and 23 rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by Darras (USPN 5,817,433), the Examiner cites that Darras teaches a composition of particulate matter of powders of metal compounds such as silicon carbide coated in polymeric material so as to form aggregates of microspheres coated in polymer, thereby forming macrospheres. The Examiner cites the abstract, Figure 2, and column 2 of Darras.

Darras teaches: "A surgical glove and method for making same comprised of a polymeric matrix with at least one compact layer of very small particulate characterized by a very high hardness disposed therein. The proposed particulate is one of a series of powders such as silicon carbide, carborundum, or diamond dust having a mean particle size of between 1-85 microns and a preferred particle size of between 5-8 microns, which can be applied to a curing elastic glove via spray or pre-mixing the particulate in the molten polymeric matrix prior to forming. The estimated thickness of the finished glove is approximately 2-7 millimeters, although greater thicknesses can be achieved by repeated processing at a cost of superior tactility but without loss of elasticity. More protection can be achieved by generating multiple layers of particulate sandwiched between layers of the polymer matrix."

As taught in Darras, the particulate is one of a series of

powders such as silicon carbide, carborundum, or diamond dust. The particulate powder or dust, as taught in Darras, has no specific shape. Powder or dust is a random mixture of various geometric shapes. Darras does not teach nor is there a description in Darras of any spherical shape of any of the particles. Further, Darras does not teach nor describe an aggregate of such particles forming a spherical shape. Darras throughout never uses the words: "sphere", "spherical", "Microsphere", or "Macrosphere". Further, there is no language to suggest or teach any specific microstructure of the particulate material, that would suggest the organization of the particulate material into any fixed form such as a spherical shape, or an aggregate of Microspheres to form a Macrosphere, as taught in the present invention.

Darras teaches away from the present invention, because the present invention has particular shaped structures: macrospheres. Macrospheres do not form themselves spontaneously out of a "soup" of a polymer and powders such as silicon carbide, carborundum, or diamond dust.

As described in the present invention Microspheres are used to form Macrospheres. Microspheres are formed in a special machine such as a "Spherisator", at a temperature of 2,000 F (for alumina). (See FIG. 12 of the present invention, and page 17 lines 2 to 20.) Once formed, they are then used to fabricate Macrospheres.

The Macrospheres can be formed by the same special machine "Spheristator" from Microspheres blended with a thermoplastic polymer, but at temperature of about 500 F. (See FIG. 13 of the present invention, and page 17 line 21 to page 18 line 5, and page 18 lines 6 to 18.) The resulting Macrospheres are perfectly spherical aggregates of the Microspheres and the polymer, as shown in FIG. 8. The microstructure of the Macrospheres is inventive and provides the puncture resistant properties of the present invention.

A glove shape is formed by either injection molding or a dipping method. In either case, a structure is created by self assembly of the Macrospheres into a hexagonal stacking pattern. An elastomer then maintains the Macrospheres in the hexagonal position, and also the glove shape of the article. (See FIG. 18-25, and page 20, line 21 to page 27 line 25 of the present invention.)

Darras does not teach nor describe any mechanism to produce "capture" of a needle point by the particulate powders of silicon carbide, carborundum, or diamond dust. The particulate taught by Darras would be pushed aside by the wedge shape of a needle point. His reference to "high resistance" to needle puncture, would be better phrased as higher resistance than using just polymer alone.

By contrast, the present invention teaches a specific microstructure for the Macrosphere, which is an aggregate of Microspheres <u>forming</u> a Macrosphere, as described in FIGs. 4-11, page 14 line 5, to page 17 line 1. FIGs. 8 to 11 and page 15 line 7 to page 17 line 1, describe the Macrosphere's "capture mechanism", which is a result of its specific microstructure. There is a positive puncture resistance and needle-stopping action when the needle enters and is captured by a Macrosphere. Once the needle point is "captured" by a Macrosphere, the sharp point is blunted by the Macrosphere attached to it, and the needle cannot pass through the glove wall.

Again, it is the microstructure of the Macrosphere, formed of Microspheres, which provides puncture resistance.

In summary, Darras does not teach the present invention and in fact teaches away from the present invention by suggesting no microstructure, but rather just powder or dust particles. Thus, the present invention is not anticipated by Darras 5,817,433.

With regard to Claims 1-6, 11-15, and 23 rejected by the Examiner under 35 U.S.C. 102(b) as being clearly anticipated by

Oakley (USPN 6,080,474), the Examiner cites that the prior art discloses polymeric articles such as surgical gloves having improved cut resistance, and comprising hard filler material which may be round shaped, in a coating of polymeric material. The Examiner cites columns 4, 5, 7, and 8 of Oakley.

Oakley teaches "A polymeric article having improved cut-resistance composed of (A) an initial polymeric article having cut-resistant properties; and (B) a cut-resistant elastomeric coating disposed on an outer surface of the initial polymeric article, <u>wherein the elastomeric coating is composed of an elastomer and a hard filler distributed in the elastomer</u>. The hard filler has a Mohs Hardness value of at least about 3. The final polymeric article has improved cut-resistance, improved flexibility, and improved comfort and will retain its properties when routinely laundered. The article is preferably in the form of a polymeric textile article, more preferably in the form of an elastomeric protective garment, and most preferably in the form of gloves, e.g., surgical gloves."

Oakley in column 4 teaches:

"The hard filler particles may be in the form of flat particles (i.e., platelets), elongated particles (i.e., needles), irregularly-shaped particles, or round particles. Preferably, the hard filler particles are in the form of platelets because platelets are more efficient in imparting cut-resistance.

The particle size of the hard filler particles preferably ranges from about 1 to about 5 microns. For flat or elongated particles, the particle size refers to the length along the long axis of the particle (i.e. the long dimension of an elongated particle or the average diameter of the face of a platelet).

The hard filler distributed in the elastomer polymer is preferably a metal or metal alloy, a ceramic material or a crystalline mineral. Suitable metals include, e.g., tungsten,

copper, brass, bronze, aluminum, steel, iron, monel, cobalt, titanium, magnesium, silver, molybdenum, tin and zinc. Non-limiting examples of suitable crystalline minerals include baddeleyite, chloritoid, clinozoisite, chondrodite, euclasite, petalite, sapphire, spodumene, staurolite, and clay. Suitable ceramic materials include, e.g., glass and alumina. Most preferably, the hard filler used in the elastomeric coating of this invention is alumina."

The "round" particle of Oakley is only one of a multitude of shapes and is not identified as a "Macrosphere", which as described above has a specific microstructure. The round particles have no specific structure other than being round and do not have any capture mechanism.

The round particles and particles of other shapes as taught in Oakley are similar to the powders and dust of Darras. No internal specific structure of the particles and no capture mechanisms are taught.

Oakley does not teach nor describe any mechanism to produce "capture" of a needle point by the hard filler, whether the hard filler is round or otherwise. The hard fillers taught by Oakley would be pushed aside by the wedge shape of a needle point, in the same fashion as the powders and dust taught by Darras.

In fact in column 4, Oakley specifically states that: "Preferably, the hard filler particles are in the form of platelets because platelets are more efficient in imparting cut-resistance." Cut resistance is distinctly different than puncture resistance. Resisting a cut is inherently easier than resisting a puncture, because when cutting the pressure is distributed across the blade in contact with the item being cut. In contrast, when a sharp instrument is being used to puncture an item, all the pressure is concentrated at the point of the sharp instrument. It takes less force to puncture an item than to cut an item. Or put another way, for a given

cutting or puncture force, it is easier to protect against a cut than a puncture. Oakley never teaches that his invention is puncture resistant.

In contrast, the present invention teaches a specific microstructure, which is an aggregate of Microspheres <u>forming</u> a Macrosphere, as described in FIGs. 4-11, page 14 line 5, to page 17 line 1. FIGs. 8 to 11 and page 15 line 7 to page 17 line 1, describe the Macrosphere's "capture mechanism", which is a result of its specific microstructure. There is a positive puncture resistance and needle-stopping action when the needle enters and is captured by a Macrosphere. Once the needle point is "captured" by a Macrosphere, the sharp point is blunted by the Macrosphere attached to it, and the needle cannot pass through the glove wall.

Oakley does not teach the present invention and in fact teaches away from the present invention by teaching only round and other shaped fillers, which do not anticipate the specific microstructure of the Macrosphere of the present invention. Thus, the present invention is not anticipated by Oakley 6,080,474.

The present invention is also not obvious in view of Oakley 6,080,474. The Examiner states that Oakley "teaches that a polymer used in making the composite surgical glove may be a polyolefin such as PE, and the coated filler may be a round-shaped metal such as claimed in an array(s) of coated fillers which obviously forms Macrospheres". The Examiner references columns 4-5 and 7-8 of Oakley.

A search of the Oakley '474 for the term array is fruitless. Oakley never uses the term array. A search for similar synonyms in the Oakley patent such as matrix also is fruitless.

The Examiner's statement "coated fillers which obviously forms macrospheres" is not supported by the language used by Oakley. Nothing in Oakley is taught or implied that would make

the specific microstructure of Macrospheres obvious.

Oakley does not ever claim puncture resistance as a property of the final article, but only cut resistance. Structurally and geometrically, as in Darras, there is no specifically formed microstructure of the material. In Oakley as in Darras there is simply a mixture formed en mass, "to provide a uniform distribution of the filler in the elastomer" (Oakley col. 4 lines 63-64).

Also in Oakley (Col. 5&6) is a section on the formation of a cut resistant fiber, formed by " melt-spinning" of the hard filler and a polymer. The fiber so formed can then be knitted or woven into the desired shape. None of these fiber materials show any structural similarity to the present invention.

The only common element between Darras, Oakley and the present invention is that they all are composites of polymer or elastomer and objects in the polymer. In Darras the objects are unstructured powder or dust, in Oakley the objects are of various shapes, including round, but only in the present invention are the objects Macrospheres, which have a specific microstructure that gives the Macrospheres a capture property. The present invention's specific microstructure and the resulting capture mechanism, is what provides puncture resistance.

Puncture resistance is a long-standing problem and the present invention provides a solution to this long-standing problem. Oakley does not even address this problem, makes no claim to solve this problem and teaches away from the present invention by suggesting no microstructure of the hard filler. Thus, the present invention is not obvious in view of Oakley.

The invention has not been anticipated and is not obvious to a person skilled in the state of the art, because the invention solves the long standing need of providing a flexible and elastic puncture proof material, which has capture devices that can capture a skidding sharp instrument such as a needle

to prevent injury to a non protected part of the body.

Independent claims 1, 11, 18, 23, and 26 have been amended. The amended claims have not been anticipated by any of the references nor are they made obvious by any of the references.

Independent claim 1 is for a puncture and cut resistant material comprising a plurality of substantially spherical macrospheres, each macrosphere comprising: a plurality of substantially spherical microspheres; and a polymer surrounding and aggregating the microspheres together to form the substantially spherical macrosphere.

Neither Darras nor Oakley nor both references taken together teach or make obvious a puncture resistant material having the micro structure of the Macrosphere as claimed in independent claim 1.

Independent claim 11 is for a puncture and cut resistant material comprising: a plurality of substantially spherical macrospheres, each macrosphere comprising: a substantially spherical porous structure having a porous surface comprising a plurality of random pores; and a polymer coating over the porous structure; wherein the polymer coating over the porous structure forms a substantially spherical macrosphere having a substantially smooth surface.

Neither Darras nor Oakley nor both references taken together teach or make obvious a puncture resistant material having the structure of the macrosphere of claim 11.

Independent claim 18 is for a puncture and cut resistant surgical glove comprising: a plurality of overlaying arrays of adjacent substantially spherical macrospheres, each macrosphere having a plurality of capture devices, each capture device adapted to capture a point of an invading sharp instrument. Each substantially spherical macrosphere having a plurality of capture devices comprises: a plurality of microspheres; and a polymer surrounding and aggregating the microspheres together;

wherein each capture device comprises an area between adjacent microspheres and the polymer surrounding the adjacent microspheres; wherein the plurality of microspheres and surrounding polymer create a plurality of capture devices surrounding the macrosphere; and wherein each capture device is adapted to capture a point of an invading sharp instrument. An elastomer encapsulates the plurality of overlaying arrays of adjacent macrospheres.

Neither Darras nor Oakley nor both references taken together teach or make obvious a puncture resistant material having substantially spherical macrospheres with the above microstructure adapted to capture a point of an invading sharp instrument as in claim 18.

Independent claim 23 is for a method of producing a puncture and cut resistant material comprising the steps of: forming a plurality of substantially spherical macrospheres, each macrosphere having a plurality of capture devices, each capture device adapted to capture a point of an invading sharp instrument; and injecting the macrospheres and an elastomer into an injection mold. Claims 24 and 25 detail the methods of forming capture devices.

Neither Darras nor Oakley nor both references taken together teach or make obvious the methods of claims 23, 24 and 25 of producing a puncture resistant material with substantially spherical macrospheres having a plurality of capture devices adapted to capture a point of an invading sharp instrument.

Independent claim 26 is for a method of producing a puncture and cut resistant material comprising the steps of: forming magnetically sensitive substantially spherical macrospheres, each macrosphere having a plurality of capture devices, each capture device adapted to capture a point of an invading sharp instrument; dipping a former comprising electro-magnetic elements into a solution of the magnetically sensitive

macrospheres and an elastomer; and activating the electro-magnetic elements; whereby activating the electro-magnetic elements draws the magnetically sensitive macrospheres onto surfaces of the former. Claims 27 and 28 detail the methods of forming capture devices.

Neither Darras nor Oakley nor both references taken together teach or make obvious the methods of claims 26, 27 and 25 of producing a puncture resistant material with magnetically sensitive substantially spherical macrospheres, each macrosphere having a plurality of capture devices adapted to capture a point of an invading sharp instrument and the other steps of claim 26.

It is requested that claims 1, and 3-18, and 21-29 be examined in light of the above and it is respectfully submitted that these claims are now in condition for allowance.

Respectfully submitted,

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